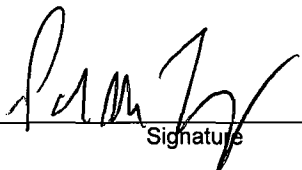


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 05986/100K504-US1	
	Application Number 10/624,942-Conf. #7691	Filed July 21, 2003	
	First Named Inventor Marco Pappagallo		
	Art Unit 1617	Examiner J. M. Kim	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>52,392</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> <p> _____ Signature Paul M. Zagar _____ Typed or printed name (212) 527-7700 _____ Telephone number February 25, 2008 _____ Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<input type="checkbox"/> *Total of <u>1</u> forms are submitted.			

Customer No. 07278

Docket No.: 05986/100K504-US1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Marco PAPPAGALLO

Application No.: 10/624,942

Confirmation No.: 7691

Filed: July 21, 2003

Art Unit: 1617

For: TREATMENT OF SPINAL MECHANICAL  
PAIN

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Examiner: Jennifer M. KIM

**REASONS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request reconsideration of this application in view of the following reasons in support of Applicants' Pre-Appeal Brief Request for Review. Claims 1-11 are pending and at issue.

In the Office Action dated November 29, 2007, claims 1-3, 5-9, and 11 were rejected under 35 U.S.C. § 102(a) as anticipated by Geusens et al., *J of Clin Densitometry*, 2001;4:389-394 ("Geusens"); and claims 1, 4 and 10 were rejected under 35 U.S.C. § 103(a) as obvious over Urban et al., *Society for Neuroscience Abstracts*, 2001;27(1):1326 ("Urban") in view of U.S. Patent No. 6,676,970 ("Bader").

### **The Anticipation Rejection of Claims 1-3, 5-9 and 11**

With respect to claims 1-3, 5-9, and 11, the Examiner contends that Geusens discloses the case history of an 18-year old boy treated with intravenous pamidronate (a biphosphonate) for extreme back pain resulting from multiple vertebral fractures (*see*, Office Action dated November 29, 2007, p. 4). The same rejection was also made in the Office Actions dated October 6, 2006 (p. 2); March 5, 2007 (p. 5); and August 6, 2007 (p. 5). The Examiner alleges that the vertebral fracture back pain disclosed in Geusens encompasses the instant claims “because the term vertebral is referred to the spinal column.” Office Action dated November 29, 2007, p. 5. *See also*, Office Action dated October 6, 2006, p. 2 (“The teaching from Geusens et al. that the boy suffered from vertebral fracture back pain encompasses Applicant’s limitation of spinal mechanical pain because the term vertebral is referred to spinal column.”).

### **The Obviousness Rejection of Claims 1, 4 and 10**

With respect to claims 1, 4 and 10, the Examiner contends that Urban discloses that zoledronate (a bisphosphonate) produces an anti-allodynic effect in rats, and Bader discloses parental zoledronate preparations. According to the Examiner, it would have been obvious to one of ordinary skill in the art to use intravenous zoledronate to treat pain based on these references (*see*, Office Action dated November 29, 2007, p. 5-6). This rejection was also made in the Office Actions dated October 6, 2006 (p. 3); March 5, 2007 (p. 6); and August 6, 2007 (p. 6).

### **Remarks and Arguments**

The instant application includes one independent claim, which reads:

1. A method of treating **chronic spinal mechanical pain** which comprises intravenously administering to a subject in need of **chronic spinal mechanical pain** relief an effective amount for relieving spinal mechanical pain of a bisphosphonate.

(emphasis added). The claim term “chronic spinal mechanical pain” is expressly defined in the specification at p. 7, ll. 15-16 as follows: “The term ‘chronic spinal mechanical pain’ is defined as any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture.” Thus, the Applicant acted as his own lexicographer by clearly setting forth an express definition of the claim term “chronic spinal mechanical pain.”

In the amendments dated January 8, 2007 (p.3-4); June 5, 2007 (p.3-4); and September 25, 2007 (p. 3-4); the Applicant argued that claims 1-3, 5-9 and 11 are not anticipated because Geusens does not disclose the treatment of back pain lasting more than twelve weeks which is not caused by cancer or an osteoporotic compression fracture. A Declaration of Dr. Marco Pappagallo Under 37 C.F.R. 1.132 (“Pappagallo Declaration”) was submitted with the June 5, 2007 Amendment. The Pappagallo Declaration states that the patient described in Geusens has osteoporotic vertebral compression fractures. Pappagallo Declaration, p. 2, para. 13-14. The Examiner found the Pappagallo Declaration to be persuasive on this point (*see*, Office Action dated August 6, 2007, p. 3).

The Examiner maintained the anticipation rejection because she did not assign the definition of “chronic spinal mechanical pain” expressly set forth in the specification, alleging that to do so would improperly read a limitation from the specification into the claim (*see*, Office Action dated August 6, 2007, p. 3; Office Action, dated November 29, 2007, p.3). Applicant respectfully asserts that this is legal error.

It is well established that a patentee may “act as his own lexicographer,” defining claim terms to have meanings separate from their ordinary meanings. *See*, MPEP 2111.01(IV) (“An applicant is entitled to be his or her own lexicographer”); *see also*, *Abraxis Bioscience, Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370, 1376 (Fed. Cir. 2006). The specification is “the single best guide to the meaning of a disputed term.” *See*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc). MPEP §2111.01(IV) states: “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.” Thus, when an applicant has acted as his own lexicographer, the law and patent rules require that the definition provided in the specification be applied.

Here, the Applicant clearly and explicitly defined “chronic spinal mechanical pain” in the specification. Indeed, the specification announces that what follows this term is a definition: “The term ‘chronic spinal mechanical pain’ **is defined as** ...” Specification, p. 7, l. 15 (emphasis added). *See*, *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 39 USPQ2d 1573 (Fed. Cir. 1996) (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”).

The patient disclosed in Geusens had back pain resulting from osteoporotic vertebral compression fractures for which he was immobilized for 3 months and then treated with calcitonin for 2 weeks before pamidronate treatment was started (*see* Geusens p. 390, 1<sup>st</sup> col. ll. 17-18, 1<sup>st</sup> col. l. 44 – 2<sup>nd</sup> col. l. 3; Pappagallo Declaration, p. 2, para. 13-14). Thus, , the rejection under 35 U.S.C. § 102(a) should be withdrawn because the present claims are directed to methods of treating a type of pain that excludes cancer pain and osteoporotic compression fracture pain lasting more than 12 weeks.

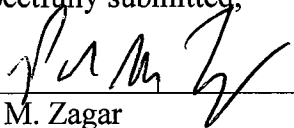
As to the rejection under 35 U.S.C. § 103(a), Urban is limited to the treatment of bone cancer-induced pain in rats using zoledronate (*see*, Urban, ll. 9-10). Bader does not cure the deficiencies of the primary reference because Bader discloses treating osteoporosis using bisphosphonates, but does not disclose using biposphonates to treat pain. The Applicant has repeatedly argued that claims 1, 4 and 10 are not obvious over Urban and Bader because no combination of Urban and Bader discloses or suggests treating “chronic spinal mechanical pain,” as this term is expressly defined by the inventors at page 7, lines 15-16 of the present specification (*see, e.g.*, Response to Non-Final Office Action dated September 25, 2007, p. 5). The Examiner has repeatedly maintained the rejection 35 U.S.C. § 103(a) because she did not assign the definition of “chronic spinal mechanical pain” expressly set forth in the specification, alleging that to do so would improperly read a limitation from the specification into the claim (*see, e.g.*, Office Action dated November 29, 2007). As explained in detail above, the Applicant has acted as his own lexicographer by explicitly providing a definition of the claim term “chronic spinal mechanical pain” in the specification. “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.” MPEP §2111.01(IV). When the Applicant’s lexicography is properly applied to the claim, no combination of Urban and Bader disclose or suggest a method of treating chronic spinal mechanical pain comprising intravenously administering to a subject in need of chronic spinal mechanical pain relief an effective amount for relieving spinal mechanical pain of a bisphosphonate. Accordingly, claims 1, 4 and 10 are not obvious over Urban and Bader; and Applicant respectfully requests that this rejection be withdrawn.

In view of the above remarks, Applicant respectfully submits that the application is in condition for allowance.

Dated: February 25, 2008

Respectfully submitted,

By

  
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